4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-2610]

A List of Biomarkers Used as Outcomes in Development of FDA-Approved New Molecular Entities and New Biological Therapeutics (October 2007 to December 2015); Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the establishment of a docket to receive suggestions, recommendations, and comments from interested parties (such as academic researchers, regulated industries, consortia, and patient groups) on a list of biomarkers that were used as outcomes to develop FDA-approved new molecular entities (NMEs) and New Biological Therapeutics from October 2007 to December 2015. Comments received on this list will help FDA determine the utility of the list and may assist FDA in developing databases on biomarkers for drug development in the future.

DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to

http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-N-2610 for "A List of Biomarkers Used as Outcomes in Development of FDA-Approved New Molecular Entities and New Biological Therapeutics (October 2007 to December 2015); Establishment of Public Docket." Received comments will be placed in the docket and, except for those

submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Marianne Noone, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 4528, Silver Spring, MD 20993-0002, 301-796-2600.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is committed to support more efficient drug development by providing scientific, technical, and regulatory advice to stakeholders (such as to pharmaceutical industries, academia, patient advocacy groups, and consortia). As part of this commitment, FDA is providing a list of biomarkers that were used as outcomes in the development of FDA-approved NMEs and New Biological Therapeutics in different disease areas from October 2007 to December 2015. This list is intended to provide examples of biomarkers that were accepted and used as endpoints in clinical trials for drug and biologic approvals from October 2007 to December 2015. This list, along with brief background information, is accessible at Biomarkers Used as Outcomes in Development of FDA-Approved Therapeutics (October 2007 to December 2015).

II. Establishment of a Public Docket and Request for Comments

FDA is soliciting suggestions and comments from stakeholders to determine the utility of the biomarker outcomes list and to identify any areas of improvement for disseminating information on biomarkers that have been used to support the approval of drugs or biologics. Specifically, FDA welcomes comments regarding the following two areas:

- Areas of improvement for communicating and disseminating information about biomarkers and their utility as drug development tools.

- The best approach for updating the biomarkers outcomes list, including any modifications of the list, in the future.

FDA will consider all comments submitted but will generally not respond directly to the person or organization submitting the comment.

Dated: September 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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